CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF TOXIC SUBSTANCES CONTROL
Final Decision to Certify a Hazardous Waste Environmental Technology

The California Environmental Protection Agency, Department of Toxic Substances Control (DTSC) hereby certifies the following company's hazardous waste environmental technology:

INFICON®, INC. HAPSITE® Portable Gas Chromatograph Mass Spectrometer, a Field and Laboratory Instrument for the Measurement of Volatile Organic Compounds.

California Health and Safety Code section 25200.1.5 authorizes DTSC to certify the performance of hazardous waste environmental technologies. Hazardous waste environmental technologies are certified pursuant to regulations found in Title 22 of the California Code of Regulations (CCR 22), Chapter 46, section 68000 et seq. Only technologies that are determined not to pose a significant potential hazard to the public health and safety or to the environment when used under specified operating conditions may be certified. The purpose of the certification program is to provide an in-depth, independent review of technologies to facilitate regulatory and end-user acceptance and to promote and foster growth of California's environmental technology industry.

DTSC makes no express or implied warranties as to the performance of the manufacturer's product or equipment. The end-user is solely responsible for complying with the applicable federal, state, and local regulatory requirements. Certification does not limit DTSC's authority to require additional measures for protection of the public health and the environment.

By accepting certification, the manufacturer assumes, for the duration of certification, responsibility for maintaining the quality of the manufactured equipment and materials at a level equal or better than was provided to obtain certification and agrees to be subject to quality monitoring by DTSC as required by the statute under which certification is granted.

DTSC's proposed decision to certify was published in the California Regulatory Notice Register, Volume 2004, No. 4-Z, pages 95-97, of January 23, 2004 and has been subject to public review and comment. Written comments were not received.

An Evaluation Report supporting the Department's decision is available for review at the Hazardous Materials Laboratory and can be emailed upon request to Dr. Ruth Chang (see below) or can be obtained from DTSC web site (http://www.dtsc.ca.gov/ScienceTechnology/index.html).
California Environmental Protection Agency, Department of Toxic Substances Control, Hazardous Materials Laboratory, 700 Heinz Avenue, Berkeley CA 94710 - 2737, Attn.: Dr. Ruth R. Chang (510) 540-2651, rchang@dtsc.ca.gov.

A description of the technology to be certified, the proposed certification statement, and the certification limitations for the technology of the company listed above follow.

CERTIFICATION PROGRAM FOR HAZARDOUS WASTE ENVIRONMENTAL TECHNOLOGIES

TECHNOLOGY CERTIFICATION

Technology:

HAPSITE® Portable Gas Chromatograph Mass Spectrometer, a Field and Laboratory Instrument for the Measurement of Volatile Organic Compounds.

Manufacturer:

INFICON®, Inc., Two Technology Place, East Syracuse, NY 13057, Tel. 800-223-0633, http://www.INFICON.com

Technology Description

HAPSITE technology is based on the principle of quadrupole GC/MS, using high-energy electron impact ionization. The sample components are separated by a gas chromatograph (GC) column and passed into a mass spectrometer (MS) via a membrane interface. The selective membrane is permeable for volatile organic compounds (VOCs), but excludes inorganic constituents, such as nitrogen gas, from the MS. Compound identifications are based on matching ion spectra in the National Institute for Standards and Technology (NIST) library. The HAPSITE is designed to analyze volatile organics in a gas phase. In conjunction with a headspace equilibrium sampling accessory, the instrument has the capability to detect the chemical equilibrium concentration in the vapor phase to measure VOCs from liquid and solid samples. The technique applies to chemicals typically with molecular weights of 45 to 300 amu, and with boiling points approximately from -50ºC to +180ºC. The internal standard gas is used as mass calibrator for compound identification and quantitation. The HAPSITE system is lightweight, completely self-contained and portable for field applications. In the field-portable mode, with a hand control unit, the analysis can be performed at the sampling point for emergency response. In the transportable mode, the HAPSITE mounted on a service module can be operated in a van for on-site analysis. In the stationary mode, the HAPSITE can be set up as laboratory equipment by using the carrier gas from a high-pressure cylinder. The instrument is loaded with software for automatic instrument calibration and with methods for sampling and analysis. The analytical procedures for air (including vapor and gas), water, and soil analysis are established by INFICON for environmental applications.

Certification Statement

Under the authority of section 25200.1.5 of the California Health and Safety Code, the Department hereby certifies the performance of the HAPSITE Portable Gas Chromatograph - Mass Spectrometer manufactured by INFICON, Inc, as a Field and Laboratory Technology for the measurement of volatile organic compounds in environmental media as specified herein. According to the standard operating procedures established by the manufacturer, the HAPSITE system is capable of measuring most of the compounds listed under EPA Method 8260B in air, water, soil and soil gas.

The HAPSITE Practical Quantitation Limits (PQLs) are compound and matrix specific. INFICON defines the Practical Quantitation Limit as the lower bound of the calibration range and represents a peak-to-peak signal to noise ratio of 10:1. For those chemicals specified by INFICON, the HAPSITE

Practical Quantitation Limits are 5 to 20 µg/L for water analysis, 0.2 to 0.5 ppmv for vapor phase analysis, and 10 to 40 µg/kg for soil analysis. Under normal environmental conditions, the relative standard deviation (RSD) of replicate analysis is expected to be = 20% and the recoveries expected to be ± 25% of the spiked values over the instrument calibration range. With an established 5-point calibration curve and appropriate quality control and quality assurance (QA/QC) program, the groundwater data obtained from HAPSITE analysis are comparable to that of EPA Method 8260B. The air QC study and the soil gas analysis of VOC contaminated sites indicated the HAPSITE data were well correlated to that of EPA Method TO-14 and Method TO-15. Relative to laboratory methods, GC and GC/MS, the HAPSITE has greater dynamic range to analyze samples up to ppm or percent level without over-saturating the instrument. For soil analysis, the HAPSITE reported values obtained from proficiency testing for the high and low level soil were within the acceptable limits established by Resource Technology Corporation (RTC), the proficiency test sample provider approved by the National Voluntary Laboratory Accreditation Program (NVLAP). However, due to the heterogeneity of environmental soil, the applications of HAPSITE on soil analysis based on equilibrium sampling warrants further investigations that analyze a wide range of VOCs in different soil types at various concentration levels. The HAPSITE measurement system has been demonstrated to be a viable cost effective technology to support site characterization, cleanup and remediation activities.

The HAPSITE is specifically designed for field use. With the advantages of fast on-site analysis, the INFICON HAPSITE significantly improves the sample turnaround time to generate data in a timely manner for the protection of public health and the environment.

Limitations of Certification

The Department makes no express or implied warranties as to the performance of the manufacturer's product or equipment. The Department has not conducted all the bench or field tests to confirm the manufacturer's performance data. Nor does the Department warrant that the manufacturer's product or equipment is free from any defects in workmanship or material caused by negligence, misuse, accident, or other causes.

The Department believes, however, that the manufacturer's product or equipment can achieve performance levels set out in this Certification. Said belief is based on a review of the data submitted by the manufacturer and other information (See "Basis for Certification" below), and is also based on the use of the product in accordance with the manufacturer's specifications.

This certification is subject to the regulations found in Title 22 of the California Code of Regulations (CCR 22), Chapter 46, section 68000, which include the duration of the Certification, and the procedures for certification amendments and decertification.

By accepting this Certification, the manufacturer assumes for the duration of the Certification, responsibility for maintaining the quality of the manufactured materials and equipment at a level equal or better than was provided to obtain this Certification and agrees to be subject to quality monitoring by the Department as authorized by the law under which this Certification is granted.

Specific Conditions

INFICON shall follow their established QA/QC program to ensure that the materials used in manufacturing and the quality of instrument meet the standards certified under ISO-9001.

INFICON shall maintain their standards for ensuring that users receive appropriate training in operation and maintenance of the instrument. For environmental applications, the method detection limit or quantitation limit, precision, and bias of the HAPSITE technology must be evaluated to ensure meeting the project-specific requirements. The surrogate compounds must be added to the environmental medium to evaluate the matrix effects and to validate the instrument performance. The analysis of blank samples must be performed as necessary to minimize cross-contamination. The quality control samples must be included in the operation as specified in the quality assurance project plan.

Through updates of user guides, the manufacturer shall inform the user of environmental and experimental parameters which potentially affect the performance of the system, as they become known to the manufacturer.

Users should follow the manufacturer's instructions for installation, operation, and maintenance of the instrument. Users should develop and follow a plan in accordance with their facility's quality management system for validating the system at appropriate intervals according to the guidance set for the HAPSITE system.

Basis for Certification

The proposed certification of this technology is based on a comprehensive evaluation conducted by the Hazardous Materials Laboratory (HML) in the California Department of Toxic Substances Control. HML reviewed instrument performance data submitted by the INFICON and field data generated by independent third parties. In addition, HML participated in independent studies evaluating the system's performance in air and soil analyses. HML staff also contacted end users to obtain additional information on performance and reliability. An evaluation report prepared by HML provides details of the evaluation.

Recommended Applications

The INFICON HAPSITE Portable Gas Chromatograph-Mass Spectrometer is intended for the measurement of volatile organic compounds in the field and in the laboratory. The HAPSITE technology operating in accordance with conditions established by the manufacturer can serve as a viable alternative for the measurement of volatile organic compounds in the environment. Applications include: (1) long term environmental monitoring of the chlorinated and aromatic hydrocarbons in air, water and soil; (2) detection and identification of toxic chemicals and hazardous materials released from industrial incidents; (3) fast on-site analysis to expedite site cleanup activities and to increase the number of sample analyses of a site to reduce data uncertainty.

Regulatory Implications

DTSC's certification does not change the regulatory status of field and laboratory measurements for volatile organic compounds in air, water, and soil matrices. This certification is intended, however, to facilitate and encourage the acceptance of this technology where a project's data quality objectives can be met by its use. To this end, regulatory programs are encouraged to consider the Department's findings regarding this technology, depending on each program's objectives and constraints. State-regulated facilities may contact state permitting officers regarding the use of the technology for the analysis of volatile organic compounds in the field and laboratory. Other local and state government permitting authorities may take this certification under consideration when making their permitting decisions. Project managers may consider using this technology where its use can contribute to the project.

Duration of Certification

Unless amended or revoked for cause, this certification will remain in effect for three years from the date of issuance.